

REMARKS

Applicants thank the Examiner and the Supervisory Patent Examiner for the courtesies extended during the telephonic interview of July 8, 2003.

Claims 1-11 constitute the pending claims in the present application. Applicants have added a new claim, claim 11.

Amendments presented in this response are made solely to expedite prosecution of the claims in the present application. Applicants reserve the right to prosecute claims of similar or differing scope in subsequent applications. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

Election/Restrictions

Applicants have elected the group I claims and note that the examiner has considered the compounds of formula (I) wherein X is CH₂; R¹ is phenyl; R² is carboxy; R³ is hydrogen, optionally substituted alkyl, optionally substituted alkenyl, optionally substituted alkynyl; R⁴ is a group NHSO₂R¹⁵ where R¹⁵ is optionally substituted alkyl, or optionally substituted aryl; R⁵, R⁶, and R⁷ are independently selected from hydrogen or an optionally substituted hydrocarbyl group.

Applicants respectfully direct the Examiner's attention to 37 C.F.R. 1.499 which states that "[i]f the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may require the applicant . . . to elect the invention to which the claims shall be restricted." For guidance on unity of invention of Markush claims, Applicants respectfully direct the Examiner's attention to the Administrative Instructions under the PCT, Annex B, Example 18. Example 18 sets out a claim to a compound having an indolyl moiety with four substituent groups, R¹-R⁴. The compounds are useful as pharmaceuticals for enhancing the capacity of blood to absorb oxygen. Example 18 concludes that unity of invention is present as "the indolyl moiety is the significant structural element which is shared by all of the alternatives" and "all the claimed compounds are alleged to possess the same utility."

Applicants respectfully submit that the situation presented in Example 18 is very similar to the present case. The claimed compounds include an indolyl moiety as "the significant structural element which is shared by all of the alternatives" and are alleged to possess the same utility of "antagonizing an MCP-1 (Monocyte Chemoattractant Protein-1) or RANTES (Regulated upon Activation, Normal T-cell Expressed and Secreted) mediated effect in a warm blooded animal." Accordingly, unity of invention is present in the current claims.

A search for the elected compounds cited above apparently did not find any relevant prior art as the Office Action of April 3, 2003 did not reference any art or make any art based rejections. Accordingly, as unity of invention exists between the elected compounds and the claims, Applicants respectfully request that search and examination be extended to the full scope of the claims as presently amended.

Claim Rejection – 35 U.S.C. § 101

Claim 10 is rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process. Applicants have amended claim 10 to recite steps involved in the method, thereby rendering moot the Examiner's rejection. Applicants request reconsideration and withdrawal of the rejection in light of the claims as amended.

Claim Rejection – 35 U.S.C. § 112

Claim 8 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants have amended claim 8 by deleting part (b). Amendments presented in this response are made solely to expedite prosecution of the claims in the present application.

Applicants submit that one skilled in the art would clearly recognize that "reacting a compound of a compound of formula (VII) with a compound of formula (VIII)" as required by claim 8 to be an acylation or sulfonylation reaction of the primary amine group of the compound of formula (VII). The undergraduate level textbook *Organic Chemistry* by Morrison and Boyd, 6th Ed. (1992) on page 858 outlines the reaction of a primary amine with an acid chloride and a

sulfonyl chloride to yield the corresponding amide and sulfonamide. *Advanced Organic Chemistry*, by Jerry March, 3rd Ed. (1985), sets out reaction conditions and cites references for the acylation of amines on pages 370-377. March specifically discusses acylation of amines by acyl halides on pages 370-371. As the Examiner concedes, the level of ordinary skill in the art is high. Applicants agree with the Examiner and submit a person skilled in the art would recognize the reaction claimed in claim 8 as a simple acylation or sulfonylation of an amine – among the most reliable reactions in the arsenal of organic chemists – and would be able to, at the very least, refer to common textbooks such as those by Morrison and Boyd or March to determine specific reaction conditions with no more than routine experimentation.

Furthermore, the specification provides ample guidance to enable a skilled artisan to practice the invention without undue experimentation. First of all, each of the substituents of formula (VII) and (VIII) is clearly defined in the specification and the claims, including leaving group Z, defined as including halo as well as mesylate and tosylate groups on page 11, line 19, and page 13, lines 1-2. Secondly, exemplary reaction conditions are given on page 11, lines 3-23. Thirdly, the starting material structures and desired product structures are recited in the claim. Based on this guidance, one skilled in the art would understand the nature of the reaction and be able to predict the probable outcome of reacting a specific compound of the formula (VII).

Accordingly, Applicants request reconsideration and withdrawal of the rejection in light of the arguments set forth above.

Claim 10 is also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for merely reciting a use without any active, positive steps delimiting how this use is actually practiced. Applicants have amended claim 10 to recite steps involved in the method, thereby rendering moot the Examiner's rejection. Applicants request reconsideration and withdrawal of the rejection in light of the claims as amended.

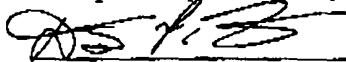
Specification

Applicants submit an abstract on a separate page as requested by the Examiner.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to Deposit Account No. 18-1945.

Respectfully Submitted,



David Halstead

Reg. No. 44,735

Date: July 21, 2003

Customer No: 28120
Docketing Specialist
Ropes & Gray LLP
One International Place
Boston, MA 02110
Phone: 617-951-7000
Fax: 617-951-7050

Atty Dkt No.: AS2D-P01471
 Via: First Class Mail
 Inventor: Faull et al.

Application No.: 09/689515
 Filing Date: October 10, 2001
 Trade: ANTI-INFLAMMATORY INDOLE DERIVATIVES

Documents Filed: Reply to Restriction Requirement (2 pages)

Change of Attorney Docket Number (1 page)

Change of Correspondence Address (1 page)

Revocation of Prior Powers of Attorney and Appointment of New Power of Attorney or
 Authorization of Agent (3 pages)

Statement Under 37 CFR 2.73(b) (1 page)

Petition for Extension of Time Under 37 CFR 1.136(a) (1 page)

Fee Transmittal (1 page)

The return receipt postcard

Sender's Initials: DYH/bxi

Date: December 2, 2002

Atty Dkt No.: AS2D-P01471

Via: First Class Mail
 Inventor: Faull et al.

Filing Date: October 10, 2001

Application No.: 09/689515

ANTI-INFLAMMATORY INDOLE DERIVATIVES

Title:

Documents Filed:
 Reply to Restriction Requirement (2 pages)

Change of Attorney Docket Number (1 page)

Change of Correspondence Address (1 page)

Revocation of Prior Powers of Attorney and Appointment of New Power of Attorney or
 Authorization of Agent (3 pages)

Statement Under 37 CFR 2.73(b) (1 page)

Petition for Extension of Time Under 37 CFR 1.136(a) (1 page)

Fee Transmittal (1 page)

This return receipt postcard

Sender's Initials: DYH/bxi

Date: December 2, 2002